

### **Remarks**

Claims 1-12 are pending in this application. Claims 1-12 are rejected.

Claim 11 is cancelled.

### **Claim Rejections - 35 U.S.C. § 103**

Claims 1-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Roser (US Patent 6,190,701) in view of Johnson (US Patent 5,376,359) and Owens, "Low GWP Alternatives to HFCs and PFCs, Report of 3M Company Speciality Materials, St. Paul, MN, USA (2000).

Applicant respectfully traverses the present rejection for the following reasons. Amended claim 1 discloses a formulation comprising an active ingredient preserved in glassy or amorphous particles. These particles are suspended in a liquid in which at least one component comprises a liquid hydrofluorinated ether, thereby facilitating the dispersion of the particles in the liquid. Independent claim 1 is amended to clarify that the provision of a liquid hydrofluorinated ether as a component of the liquid provides the technical benefit of facilitating the dispersion of the particles in the liquid of the formulation.

Roser discloses a formulation comprising a first component which includes microparticles of sugar glass containing a bioactive agent. The Roser formulation comprises a second component which contains at least one biocompatible liquid perfluorocarbon (PFC) as a continuous phase (i.e., bulk carrier agent) for the discontinuous phase. The second component consists of the microparticles of sugar glass containing a bioactive agent. A PFC is a hydrocarbon where all of the hydrogen atoms are replaced by fluorine atoms.

As the December 3, 2009 Office Action (the Office Action) has acknowledged, a difference between the presently claimed invention according to claim 1 and the formulations

of Roser lies in the use of a [hydro]fluorinated ether as the bulk carrier for suspending the glassy or amorphous particles. The Office Action states that the teachings of Johnson and Owen make it obvious to replace the PFC of Roser with a [hydro]fluorinated ether.

Contrary to the Office Action's interpretation of the teaching of Johnson, there is no specific disclosure of formulations containing a liquid hydrofluorinated or fluorinated ether. Rather, all of the examples of Johnson employ hydrofluoroalkanes (HFAs) as the (bulk) liquid component of the formulations. Furthermore, the perfluoropolyethers used in the examples of Johnson (i.e., Fomblin™) which are adsorbed onto a solid particulate drug material in the formulations are not the same as hydrofluorinated ethers as used in the present invention. Polyfluoropolyether as used in Johnson do not contain hydrogen atoms (see for example, Johnson, col. 3, ll. 66-68), whereas a hydrofluorinated ether will have at least one hydrogen atom. Although Johnson discloses an extensive list of suitable liquid propellants including several hydrofluorinated ethers (see Johnson, col. 2, ll. 48-64), there is no subsequent disclosure either by way of direct statement or experimental data to show that any of these specific hydrofluorinated ethers would provide the suspension stability properties as disclosed in the examples of Johnson which use an HFA.

Moreover, Johnson states that the HFAs 1,1,1,2-tetrafluoroethane (propellant 134a) and heptafluoropropane (propellant 227) are preferred (Johnson, col. 2, l. 68 to col. 3, l. 3). These are not hydrofluorinated ethers. The list set forth in Johnson at column 2, which broadly and without support states that "any fluorocarbon aerosol propellant" may be employed in the invention of Johnson is entirely speculative and would leave the skilled person no wiser as to whether the use of a hydrofluorinated ether would indeed provide suitable **suspension stability properties**. This is because the skilled person would look at the teaching of the specific examples of Johnson to glean information of technical merit potentially useful for formulating a strategy for making further inventions.

Furthermore, the primary objective of the teaching of Johnson identified at column 2, lines 3-14, is to establish stabilized pharmaceutical aerosol compositions using propellants 134a and 227. As evidenced by the examples, this appears to have been achieved by

Johnson whereby the incorporation of a soluble perfluoropolyether adsorbed onto a solid particulate drug material is the key inventive concept to afford suspension stability in certain HFAs, whereby previously attaining such stability was problematic.

Owens does not correct the deficiencies of Roser and Johnson. Owens discloses that hydrofluoroethers have reduced environmental effects (e.g., atmospheric lifetimes) to other fluorine-containing hydrocarbons (see, e.g., Table 2). Exemplary applications for such hydrofluoroethers include use as heat transfer agents and solvents for precision cleaning and coating deposition (see page 8). There is no disclosure in Owens of uses in stabilizing formulations containing a particulate material.

Accordingly, starting with the formulations disclosed in Roser, it was not obvious based on the teachings of Johnson and/or Owens to employ a hydrofluorinated ether in place of a PFC as a component of the liquid for dispersing particles as in the present invention. Johnson does not teach the person skilled in the art the use of hydrofluorinated ethers in suspension stabilized formulations, but rather focuses on the use of HFAs as a bulk liquid carrier of a solid drug material which has a perfluoropolyether (and not a hydrofluorinated ether) adsorbed onto its surface to impart such stabilization. Owens adds no further teaching to Roser and Johnson in establishing the obviousness of the present invention. Specifically, Owens is silent with regard to the use of hydrofluorinated ethers in facilitating suitable dispersion/suspension stabilizing properties in liquid formulations.

Accordingly, for at least these reasons, claims 1-10 and claim 12 are allowable under 35 U.S.C. § 103(a) over Roser in view of Johnson and Owens.

### **Double Patenting**

Claims 1-6, 10 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 13, and 16-18 of Roser (US Patent 6,190,701), in view of Johnson (US Patent 5,376,359).

As set forth above, Applicant has demonstrated the non-obviousness of the present invention over the combination of Roser and Johnson. Accordingly, claims 1-6 and 10-12 are allowable under the judicially created doctrine of obviousness-type double patenting over claims 1-4, 13, and 16-18 of Roser, in view of Johnson

### **Conclusion**

Applicant has made a genuine effort to respond to each of the Examiner's objections and rejections in advancing the prosecution of this case. Applicant believes that all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested. If any additional issues need to be resolved, the Examiner is invited to contact the undersigned at his earliest convenience.

The Petition fee of \$65.00 is being charged to Deposit Account No. 02-3978 via electronic authorization submitted concurrently herewith. The Commissioner is hereby authorized to charge any additional fees or credit any overpayments as a result of the filing of this paper to Deposit Account No. 02-3978.

Respectfully submitted,

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Date: April 5, 2010

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